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Genitourinary health in a population-based cohort of males with Duchenne and Becker muscular dystrophies

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Abstract

Introduction—Genitourinary (GU) health among patients with Duchenne and Becker muscular dystrophies (DBMD) has not been explored using population-based data.

Methods—Medical records of 918 males ascertained by the Muscular Dystrophy Surveillance, Tracking, and Research Network were reviewed for documentation of GU-related hospitalizations and prescribed medications. Percentages of males who received these medical interventions were calculated, hazard ratios (HR) and 95% confidence intervals (CI) were estimated for associations with sociodemographics (study site, race/ethnicity), symptoms (early-versus late-onset, ambulation status, scoliosis), and treatments (respiratory support, steroids).

Results—Among the 918 males, 81 (9%) had a GU condition; voiding dysfunction (n=40), GU tract infection (n=19), and kidney/ureter calculus (n=9) were most common. A Kaplan-Meier curve produced a cumulative probability of 27%. Cox regression showed GU conditions were more common when males were non-ambulatory (HR=2.7, 95% CI=1.3-5.6).

Discussion—These findings highlight increased awareness of GU health and multidisciplinary care of DBMD patients.

Keywords

male urogenital diseases; Duchenne muscular dystrophy; Becker muscular dystrophy; neuromuscular diseases; epidemiology

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INTRODUCTION

Duchenne and Becker muscular dystrophies (DBMD) are X-linked neuromuscular disorders caused by mutations in the *Dystrophin* gene.[1] Affected individuals experience progressive skeletal muscle weakness that typically results in loss of ambulation in the second decade of life.[2] Moreover, respiratory, orthopedic, and cardiac complications develop as disease progresses.[2] Steroid therapy delays loss of ambulation, improves pulmonary function, and may decrease the risk of scoliosis and cardiomyopathy.[3-6] Life expectancy of affected individuals has increased over the past few decades with the implementation of new approaches to care and management.[7]

Because DBMD affects multiple systems, multidisciplinary care has been recommended for management of skeletal, respiratory, cardiac, and gastrointestinal complications; speech and language delays; nutritional requirements; and pain control; however, such recommendations have not been extended to the monitoring and treatment of genitourinary (GU) conditions.[8] Moreover, GU conditions in DBMD patients have not been studied adequately and deserve further investigation.[9] A limited number of surveys of Duchenne muscular dystrophy (DMD) patients[10,11] or their caregivers[11-13] showed that 40-85% of patients experienced urinary symptoms. Review of medical records of DMD patients also documented GU conditions in these patients.[14-16] These studies[10-16] used samples from clinic populations or parent-based organizations for muscular dystrophies and were limited in sample size; thus, they may not reflect the frequency of severe GU conditions among those with DBMD.

Population-based studies of GU conditions among DBMD patients have not been reported. Using data from the population-based Muscular Dystrophy Surveillance, Tracking, and Research Network (MD STAR*net*), we estimated the percentages of DBMD males hospitalized or prescribed medication for treatment of GU conditions, and we examined factors that may have influenced risk of these conditions among this cohort.

MATERIALS AND METHODS

Study Population

The MD STAR*net* is a multisite, population-based surveillance project established in 2002. Details of the surveillance methodology have been published elsewhere.[17] Briefly, the MD STAR*net* used active case finding and medical record abstraction to ascertain individuals diagnosed with DBMD with birth dates from January 1, 1982 through December 31, 2011 and who resided in 1 of 6 sites (Arizona, Colorado, Georgia, Hawaii, Iowa, or the 12 western counties in New York State). Each participating site obtained permission for case finding either through public health surveillance authority or institutional review board approval. Trained staff abstracted records from multiple sources, such as neuromuscular clinics, hospitals, and birth defect surveillance programs, to identify individuals with DBMD.[17] Data abstracted included sociodemographic characteristics, signs and symptoms of disease, diagnostic tests and procedures, medical interventions and treatments, family history of muscular dystrophy among index cases, and data about their primary caregivers and health care providers.[17] Clinical data abstracted were reviewed by the Clinical Review

Committee, which included a neuromuscular physician from each participating site, and each case was assigned a diagnostic status of definite, probable, possible, asymptomatic, or affected female.[18] Annual follow-up record abstraction was conducted for cases until death, migration out of an MD STAR*net* site, or until December 31, 2011 for cases ascertained prior to January 1, 2011, or until December 31, 2012 for cases first ascertained in 2011. We included only male cases with a definite or probable diagnostic status in our analyses.

Identification of GU Conditions

Data on inpatient hospitalizations occurring after DBMD diagnosis were abstracted from medical records and included admission and discharge dates, reasons for hospitalization, and, if available, the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) or Current Procedural Terminology (CPT) codes. Data about medication prescribed for treatment of GU conditions were also abstracted and included the medication name and year of use; medications that were used for an acute event, a limited time period (less than 6 weeks), or prophylaxis purposes (taking antibiotics as prophylaxis for urinary tract infection) were not recorded in the MD STAR*net*. We defined a case as having a GU condition that received medical intervention if there was documentation of at least 1 GU-related hospitalization or prescribed medication. For hospitalizations, if there were multiple GU conditions recorded during the same hospital admission, the male was defined as having concurrent GU conditions. Concurrent use of medications was defined as 2 or more GU medications prescribed within the same calendar year.

Covariates

The associations between selected sociodemographic characteristics, disease symptoms, and treatments for DBMD and time to onset of a GU condition were examined. Sociodemographic characteristics included MD STAR*net* site (Arizona, Colorado, Georgia, Hawaii, Iowa, and New York State) and race/ethnicity (non-Hispanic white, non-Hispanic black, Hispanic, and other). Disease symptoms were disease phenotype (early- or late-onset, defined as whether or not the earliest symptoms occurred before the sixth birthday[19]), ambulation status (walking or not walking), and diagnosis of scoliosis (defined as spinal curvature >10 degrees). DBMD treatments examined were any use of steroid medications (including deflazacort, prednisone, and prednisolone) and any use of a respiratory assist device (including bi-level positive airway pressure, continuous positive airway pressure, or tracheotomy).

Statistical Analysis

Frequencies of hospitalizations and medications for GU conditions were calculated for all males with a definite or probable[18] diagnostic status (n=918). To investigate factors that were associated with risk of onset of GU conditions, analyses were conducted on a subsample (n=794). This subsample excluded males who met one or more of the following criteria: were younger affected siblings in an MD STAR*net* family (n=100) to reduce the impact of any potential familial influence on susceptibility or treatment of GU conditions; resided in Hawaii (n=18), because ascertainment and abstraction were conducted within a

shorter time frame and with a restricted period of follow-up compared to other MD STAR*net* sites; or had a congenital abnormality of the GU tract (n=8).

A Kaplan-Meier survival curve was used to report the cumulative probability of onset of GU conditions among MD STAR*net* males. Age-related variables were presented as mean ± standard deviation. Selected categorical variables (MD STAR*net* site, race/ethnicity, and disease phenotype) were summarized as frequencies and percentages. In addition, univariate analyses were conducted using Cox regression models to estimate hazard ratios (HRs) and 95% confidence intervals (CIs). For Cox regression, MD STAR*net* site, race/ethnicity, and disease phenotype were entered as fixed variables; ambulation status, diagnosis of scoliosis, use of steroids, and use of a respiratory assist device were entered as time-dependent variables by coding a binary status at each age follow-up abstraction was available. We also conducted additional analyses excluding males who had resided in more than 1 MD STAR*net* site (n=8) to reduce the impact of potential differences in care received at 2 different sites on the observed associations. Statistical analyses were performed using SAS 9.3 (SAS Institute, Cary, NC); $P < 0.05$ was considered to be statistically significant.

RESULTS

Medical Intervention for GU Conditions

Overall, 918 definite or probable DBMD males were ascertained from 818 families across all 6 MD STAR*net* sites. Of these 918, 55 (6.0%) had 1 or more documented hospitalizations for a GU condition (Table 1). Of these 55, the most common reasons for hospitalization were GU tract infections (n=17) and voiding dysfunction (n=13). Likewise, 35 (3.8%) were prescribed at least 1 medication for a GU condition (Table 2). Most medications were indicated for treatment of voiding dysfunction. The most frequently used drugs were oxybutynin (n=18), followed by desmopressin (n=6), and tamsulosin (n=6). Supplemental Tables S1 and S2 (available online) list the specific GU diagnoses and the specific GU medications prescribed, respectively. When hospitalization and medication data were combined, 81 out of the 918 (8.8%) males had at least 1 GU condition that received medical intervention. Of these 81, voiding dysfunction (n=40), GU tract infection (n=19), and kidney/ureter calculus (n=9) were the most common reasons for medical intervention (data not shown).

Characteristics of Oldest Males with DBMD per Family

The percentage of those with a GU condition was relatively unchanged in the subsample of 794 oldest affected males (n=68, 8.6%) compared with the full sample (n=81, 8.8%). The mean age at the last follow-up completed in the subsample was 14.9±6.2 years. For those with GU conditions, the mean age of first onset was 15.7±5.0 years. The distributions of MD STAR*net* site, race/ethnicity, and disease phenotype were similar between those with and without a GU condition (Table 3).

Among the 794 oldest affected males in the subsample, 425 (53.5%) were non-ambulatory with the mean age of ambulation loss of 11.2±2.7 years, and 330 (41.6%) had a diagnosis of scoliosis with the mean age at diagnosis of 13.1±2.6 years. Also, 436 (54.9%) had used

steroids with the mean age of first use of 7.5±2.9 years; 154 (19.4%) had used a respiratory assist device with the mean age of first use of 17.2±3.8 years (data not shown).

Factors that Influenced Risk of Onset of GU Conditions among Males with DBMD

The cumulative probability of onset of a GU condition estimated through age 30 by the Kaplan-Meier survival curve was 27% (95% CI=24-30%) (Figure 1). Univariate Cox regression showed a significantly increased risk of GU conditions among non-ambulatory males (HR=2.7, 95% CI=1.3-5.6, Table 4). Other factors, including MD STAR*net* site, race/ethnicity, disease phenotype, diagnosis of scoliosis, use of steroids, or use of a respiratory assist device were not associated significantly with GU conditions (Table 4). Also, HR estimates were unchanged when the 8 males who had resided in more than 1 site were excluded from analysis (data not shown).

DISCUSSION

In this population-based study, we observed that approximately 9% of DBMD males were hospitalized or prescribed medication for a GU condition. The Kaplan-Meier curve, estimated through age 30, produced a cumulative probability of onset of a GU condition as 27%. Voiding dysfunction was identified as the most common reason for medical intervention followed by GU tract infection and kidney/ureter calculus. In addition, we observed that loss of ambulation was associated with a significantly increased risk of onset of a GU condition in MD STAR*net* males.

Review of medical records of DMD patients attending a neuromuscular clinic located in 1 of our surveillance sites reported 67 of 135 (50%) had a urological diagnosis.[14] The higher percentage of GU conditions identified in that study[14] may be due, in part, to identification of GU conditions from outpatient medical records rather than hospitalizations and inclusion of a larger number of GU conditions which may not require hospitalization or medication, such as enuresis. In our study, voiding dysfunction was the most common GU condition for which medical intervention was received. However, our percentages were considerably lower than those of previous studies that examined self-reports of voiding-related symptoms among DMD patients.[10-13] The difference in the percentages likely reflects differences in types of information collected; previous studies looked at GU symptoms, which may or may not require treatment, whereas we examined those who received treatment (medication or hospitalization).

Several lines of evidence point to an increase in urologic dysfunction with increasing disease progression in DBMD. Askeland *et al*[14] found significant associations between certain types of GU conditions (e.g., lower urinary tract infections, nephrolithiasis) and scoliosis diagnosis, scoliosis surgery, and invasive respiratory support, milestones used as surrogates for disease progression. In our study, associations for any GU condition and scoliosis or use of a respiratory assist device were increased but were only marginally significant. However, similar to Askeland *et al*,[14] we found that wheelchair use, another marker of disease progression, was associated significantly with occurrence of any GU condition. These findings also support those by Backhouse *et al*,[12] who reported that overall urinary problems increased as mobility decreased in DMD patients. Factors that may contribute to these

observations include the need for special bathroom facilities or assistance from others for wheel chair users, which may lead to voiding postponements and potential voiding dysfunction,[20] and osteoporosis and urine stasis in non-ambulatory patients, which may contribute to their increased risk for nephrolithiasis.[14]

The physiology underlying the urinary tract dysfunction in DBMD patients is not understood fully. Detrusor overactivity has been reported in some patients,[11,21] and this may have contributed to some voiding-related conditions. A previous study[22] that evaluated urodynamics in 7 DMD patients with urinary dysfunction observed that these conditions were more often due to upper motor neuron dysfunction rather than a myopathy of detrusor or sphincter muscles; the reasons for upper motor neuron dysfunction in DMD, however, remains to be determined.[22]

Our study has some limitations. First, the MD STAR*net* did not collect data on symptoms or non-prescription outpatient management of GU conditions, or medications used for treatment of acute events. As a result, the percentage of males with GU conditions who received medical intervention reported in our study is likely to be an underestimate of the scope of the clinical problems. Second, case definitions in the MD STAR*net* did not distinguish Duchenne and Becker dystrophinopathies; instead, our disease phenotype classification was an attempt to separate those with earlier onset and more severe phenotype from those with later onset and less severe phenotype. In addition, information about non-medical management of voiding dysfunction, different voiding methods used, and results from urodynamic testing were not available in the MD STAR*net* surveillance dataset. Future studies are needed to collect data in these topics to better understand the underlying causes and management of GU conditions in this population.

CONCLUSIONS

This study of a population-based cohort of males with DBMD showed GU conditions treated by hospitalization or prescribed medication may not be uncommon. Disease progression, manifested by loss of ambulation, increased the risk of onset of these GU conditions receiving treatment. The findings highlight the need for the neuromuscular team to ask about voiding function, particularly in later stages of DBMD and to be aware of the possibility of renal stones. Urologists will need to be involved in treatment and management as symptoms are identified. Future research may investigate causes of GU dysfunction and suggest preventative measures.

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Abbreviations

CI	confidence interval

CPT	Current Procedural Terminology
DBMD	Duchenne and Becker muscular dystrophies
DMD	Duchenne muscular dystrophy
GU	genitourinary
HR	hazard ratio
ICD-9-CM	International Classification of Diseases, Ninth Revision, Clinical Modification
MD STAR*net*	Muscular Dystrophy Surveillance, Tracking, and Research Network

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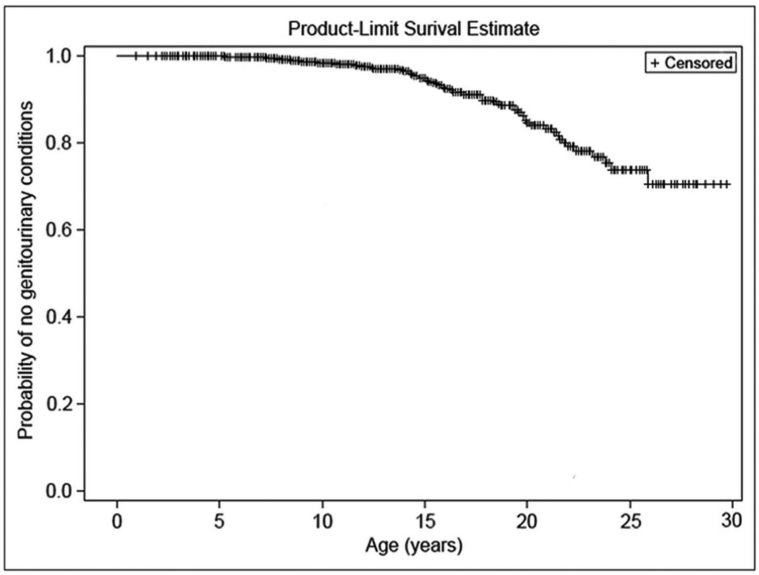

Figure 1.

Kaplan-Meier survival curve of the first genitourinary condition receiving medical intervention in males with Duchenne and Becker muscular dystrophies, Muscular Dystrophy Surveillance, Tracking and Research Network, 1982-2011.

Table 1

Recorded hospitalizations for genitourinary conditions in males with Duchenne and Becker muscular dystrophies, Muscular Dystrophy Surveillance, Tracking and Research Network, 1982-2011.

Genitourinary Diagnosis (ICD-9-CM Code) or Procedure*	Number of Males
Renal failure	*5*
Acute renal failure (584)	4
Renal failure, unspecified (586)	1
Genitourinary tract infection	*17*
Infections of kidney (590)	*2*
Cystitis (595)	1
Urinary tract infection (599.0)	15
Orchitis and epididymitis (604)	1
Genitourinary tract calculus	*8*
Calculus of kidney (592.0)	6
Calculus of ureter (592.1)	4
Voiding dysfunction	*13*
Neurogenic bladder (596.54)	1
Retention of urine (788.2)	6
Incontinence of urine788.3)	2
Frequency of urination and polyuria (788.4)	1
Oliguria and anuria (788.5)	1
Urinary hesitancy (788.64)	1
Painful urination (788.9)	1
Anatomic abnormality of genitourinary tract	*8*
Redundant prepuce and phimosis (605)	1
Anatomic abnormality of genitourinary tract	*8*
Torsion of testis (608.2)	*2*
Undescended testicle (752.5)	3
Hypospadias and epispadias (752.6)	1
Obstructive defects of renal pelvis and ureter (753.2)	1
Atresia and stenosis of urethra and bladder neck (753.6)	1
Others	*12*
Hydronephrosis (591)	3
Vesicoureteral reflex, unspecified (593.7)	1
Urethral stricture (598)	2
Hematuria (599.7)	7
Hydrocele (603.9)	1
Pyelotomy/Pyelostomy	1
Any genitourinary diagnosis	*55*

ICD-9-CM: International Classification of Diseases, Ninth Revision, Clinical Modification.

*Individual genitourinary diagnoses may not sum to the total number of diagnoses for a category due to males with multiple diagnoses within a category.

Table 2

Recorded medications prescribed for genitourinary conditions in males with Duchenne and Becker muscular dystrophies, Muscular Dystrophy Surveillance, Tracking and Research Network, 1982-2011.

Medication	Number of Males
For genitourinary tract infection	*3*
Nitrofurantoin	1
Trimethoprim	2
For voiding dysfunction *	*29*
Tolterodine	*5*
Oxybutynin	18
Solifenacin	2
Tamsulosin	6
Desmopressin	6
For genitourinary tract calculus	*4*
Urocit-K	4
Any genitourinary medication	*35*

* The sum of individual medications for voiding dysfunction is greater than the number of males with voiding dysfunction because some males used more than one type of medication.

Table 3

Characteristics of oldest affected males with Duchenne and Becker muscular dystrophies from 794 families, Muscular Dystrophy Surveillance, Tracking and Research Network, 1982-2011.

Characteristic*	With Genitourinary Conditions (N=68) n (%)	Without Genitourinary Conditions (N=726) n (%)
Current study site		
Arizona	17 (25.0)	170 (23.4)
Colorado	14 (20.6)	157 (21.6)
Georgia	10 (14.7)	208 (28.7)
Iowa	15 (22.1)	97 (13.4)
New York	12 (17.6)	94 (12.9)
Race/ethnicity		
Non-Hispanic White	43 (68.3)	439 (65.7)
Non-Hispanic Black	1 (1.6)	54 (8.1)
Hispanic	15 (23.8)	138 (20.7)
Other	4 (6.3)	37 (5.5)
Disease phenotype		
Late	15 (22.1)	145 (20.2)
Early	53 (77.9)	574 (79.8)

* The total number of males for each characteristic may be less than 794 due to missing values.

Table 4

Univariate Cox regression analysis of genitourinary conditions in males with Duchenne and Becker muscular dystrophies, Muscular Dystrophy Surveillance, Tracking and Research Network, 1982-2011.

	Hazard Ratio	95% Confidence Interval	*P* Value
Current study site			0.322
Arizona	1.0	Referent	
Colorado	0.9	[0.5, 1.9]	
Georgia	0.6	[0.3, 1.4]	
Iowa	1.5	[0.7, 3.0]	
New York	1.0	[0.5, 2.2]	
Race/ethnicity			0.390
Non-Hispanic White	1.0	Referent	
Non-Hispanic Black	0.2	[0.1, 1.5]	
Hispanic	1.1	[0.6, 2.0]	
Other	1.4	[0.5, 3.8]	
Phenotype			0.323
Late	1.0	Referent	
Early	1.3	[0.8, 2.4]	
Time-dependent variables			
Loss of ambulation	2.7	[1.3, 5.6]	0.010
Diagnosis of scoliosis	1.6	[0.9, 2.7]	0.084
Use of steroids	1.6	[1.0, 2.7]	0.077
Use of a respiratory assist device	1.8	[1.0, 3.4]	0.063